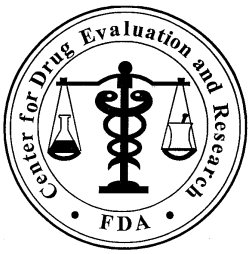
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-173

OTHER REVIEW(S)



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	July 20, 2009
To:	Thomas Laughren, MD, Division Director
	Division of Psychiatry Products (DPP)
Through:	Jodi Duckhorn, MA, Team Leader
	Division of Risk Management
From:	Latonia M. Ford, RN, BSN, MBA
	Patient Product Information Reviewer
	Division of Risk Management (DRISK)
Subject:	DRISK Review of Patient Labeling (Medication Guide)
Drug Name(s):	Zyprexa Relprevv (olanzapine pamoate) long-acting injection
Application Type/Number:	NDA 22-173
Applicant/sponsor:	Eli Lilly and Company
OSE RCM #:	2009-513

1 INTRODUCTION

This review is written in response to a request by the Division of Psychiatry Products (DPP) for the Division of Risk Management (DRISK) to review the Applicant's proposed Medication Guide (MG) for Zyprexa Relprevv (olanzapine pamoate). Please let us know if DPP would like a meeting to discuss this review or any of our changes prior to sending to the Applicant. The proposed REMS is being reviewed by DRISK and will be provided to DPP under a separate cover.

2 MATERIAL REVIEWED

- Draft Zyprexa Relprevv (olanzapine pamoate) long-acting injection Medication Guide (MG) submitted March 11, 2009, and revised by the Review Division throughout the current review cycle
- Draft Zyprexa Relprevv (olanzapine pamoate) long-acting injection Prescribing Information (PI) submitted March 11, 2009, and revised by the Review Division throughout the current review cycle

3 RESULTS OF REVIEW

In our review of the MG, we have:

- simplified wording and clarified concepts where possible,
- ensured that the MG is consistent with the PI,
- removed unnecessary or redundant information
- ensured that the Medication Guide meets the Regulations as specified in 21 CFR 208.20.
- ensured that the MG meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006).

The applicant adequately addressed the high level comments submitted by DRISK to the review division June 3, 2009. Each recommendation was addressed and corrected appropriately.

We added the section "What are the Ingredients in ZYPREXA RELPREVV?" to be consistent with other patient labeling.

Our annotated MG is appended to this memo. Any additional revisions to the PI should be reflected in the MG.

Please let us know if you have any questions.

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/s/

Latonia Ford
7/21/2009 10:42:24 AM
INTERDISCIPLINARY

Jodi Duckhorn
7/21/2009 10:45:40 AM
DRUG SAFETY OFFICE REVIEWER

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	June 18, 2009
To:	Thomas Laughren, MD Director, Division of Psychiatry Products
Through:	Todd Bridges, RPh, Team Leader Denise P. Toyer, PharmD, Deputy Director Carol A. Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Deveonne Hamilton-Stokes, RN, BSN Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Label and Labeling Review
Drug Name(s):	Zyprexa Relprevv (Olanzapine) for Extended-release Injectable Suspension
Application Type/Number:	NDA# 22-173
Applicant:	Eli Lilly and Company
OSE RCM #:	2009-514

CONTENTS

1 METHODS AND MATERIALS

The Division of Medication Error Prevention and Analysis (DMEPA) used Failure Mode and Effects Analysis[1] (FMEA) in our evaluation of the labels and labeling submitted as part of the March 11, 2009 submission (see Appendix A, B and C; no image of insert labeling).

2 RECOMMENDATIONS

Our evaluation noted areas where information on the labels and labeling can be improved to minimize the potential for medication errors. Section 2.1 *Comments to the Applicant* contains our recommendations for the container labels, diluent label and carton labeling. We request the recommendations in Section 2.1 be communicated to the Applicant prior to approval.

We would be willing to meet with the Division for further discussion, if needed. Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard to this review. If you have further questions or need clarifications on this review, please contact Bola Adeolu, OSE Regulatory Project manager, at 301-796-4264.

2.1 COMMENTS TO THE APPLICANT

We acknowledge your revisions; however, we have the following outstanding concerns. Please revise your labels and labeling accordingly.

A. Container Label, Diluent Label and Carton Labeling

1. Although we acknowledge the change in font and stroke-width of the established name, the established name stills does not have a prominence commensurate to that of the proprietary name. Revise the established name per 21 CFR 201.10(g)(2) which states: The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.
2. The revisions made to the "Relprevv" portion of the proprietary name are inadequate and still do not provide sufficient color contrast against the background color. Revise the color of the "Relprevv" portion of the name to a color that provides more contrast with the background color and increases the readability of the name. Additionally, the "Relprevv" portion of the name and the 300 mg strength share the same green color. The colors utilized for the proprietary name should not be used for product strength differentiation. When the same color is used for both the proprietary name and strength, the effectiveness of having non-overlapping distinct colors for strengths is diminished. To decrease the risk of product strength selection errors, we reiterate that you should revise the color schemes to ensure the font colors utilized for the proprietary name are not the same as any color used to differentiate the product strengths.

[1] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

B. Diluent Label

1. Although the font size of “Diluent for” has been increased, the drug name Zyprexa Relprevv still appears prominent because it is in the same color and font as the vials with the actual medication. Decrease the size of the drug name and revise the appearance of the drug name “Zyprexa Relprevv” on the diluent label through the use of alternate colors, shading, boxing, or some other means so that it is not as prominent and is not identical to “Zyprexa Relprevv” that appears on the actual medication.

2. Delete the established name (b) (4) from the Diluent label. The appearance of the established name of the active drug substance on the label increases the risk that healthcare practitioners may think the diluent vial contains the active drug.

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/s/

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6/18/2009 12:14:19 PM
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